General

Guideline Title

ACR Appropriateness Criteria® radiologic management of iliac artery occlusive disease.

Bibliographic Source(s)

Copelan AZ, Kapoor BS, AbuRahma AF, Cain TR, Caplin DM, Farsad K, Knuttinen MG, Lee MH, McBride JJ, Minocha J, Reis SP, Rochon PJ, Shaw CM, Lorenz JM, Expert Panel on Interventional Radiology. ACR Appropriateness CriteriaÂ® radiologic management of iliac artery occlusive disease. Reston (VA): American College of Radiology (ACR); 2017. 12 p. [47 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Kostelic JK, Ray CE Jr, Lorenz JM, Burke CT, Darcy MD, Fidelman N, Hohenwalter EJ, Kinney TB, Kolbeck KJ, Kouri BE, Mansour MA, Nair AV, Owens CA, Rochon PJ, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® radiologic management of iliac artery occlusive disease. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 8 p. [33 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Radiologic Management of Iliac Artery Occlusive Disease

Variant 1: Nonsmoker, sedentary lifestyle. No symptoms at rest but mild left lower-extremity claudication on walking, asymmetrically diminished left femoral pulse. Next steps on initial physician visit.

Treatment/Procedure	Rating	Comments
US duplex Doppler lower extremity	8	
Plethysmography and pulse volume recording	6	
CTA pelvis with runoff	7	
MRA pelvis with runoff	7	

Treatment/Procedure	Rating	Comments
Catheter-directed angiography	5	This procedure should be performed only at the time of endovascular therapy.
Risk factor analysis, lipid profile and ABIs	9	
No further treatment or evaluation needed	1	
Best medical management including supervised exercise program only	9	
Anticoagulation adjunctive therapy	3	
Antiplatelet adjunctive therapy	7	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Long history of mild claudication. Acute-onset left lower-extremity pain. Absent left femoral pulse on palpation, faint dorsalis pedis and posterior tibial pulses by Doppler. Next steps.

Treatment/Procedure	Rating	Comments
Ankle brachial index	8	
US duplex Doppler lower extremity	8	
Plethysmography and pulse volume recording	5	
CTA pelvis with runoff	8	
MRA pelvis with runoff	7	This procedure takes longer to perform.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Known atrial fibrillation and spine surgery 3 weeks ago. Sudden-onset right lower-extremity pain. Diminished pulses in right lower extremity. CTA demonstrates isolated filling defect in right common iliac artery.

Treatment/Procedure	Rating	Comments
Anticoagulation adjunctive therapy	7	Anticoagulation is potentially contraindicated in the setting of recent spinal surgery; clinical assessment of relative risk is imperative.
Antiplatelet adjunctive therapy	5	
Catheter-directed thrombolytic therapy	3	This procedure is probably not indicated but needs to be individualized depending on patient parameters.
Catheter-directed mechanical thrombectomy	7	This procedure needs to be individualized depending on patient parameters. It is less appropriate for larger clot burdens.
Surgical revascularization	9	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: Past medical history of heavy smoking. Severe claudication and no symptoms at rest. Angiogram demonstrates bilateral 90% common iliac artery stenosis (TASC A).

Treatment/Procedure	Rating	Comments
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Treatment/Procedure	Rating	Comments
Anticoagulation adjunctive therapy	3	
Antiplatelet adjunctive therapy	8	
Best medical management including supervised exercise program only	5	This procedure may be appropriate for initial therapy with intervention for refractory patients.
Bilateral percutaneous transluminal angioplasty only	8	This procedure is performed with selective stenting for suboptimal result.
Bilateral stent placement	8	This procedure is done primarily for some lesions depending on lesion morphology and length.
Surgical revascularization	4	This procedure may be useful as secondary therapy, especially in the event of failed endovascular procedures.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 5: Past medical history significant for diabetes mellitus, hypertension, and smoking. Increasing claudication of right lower extremity involving right buttock for last 3 months. CTA pelvis with runoff reveals short-segment occlusion of right common iliac artery (TASC B).

Treatment/Procedure	Rating	Comments
Best medical management including supervised exercise program only	2	
Primary percutaneous transluminal angioplasty alone	8	
Primary stenting	8	
Surgical revascularization	4	This procedure may be useful as secondary therapy, especially in the event of failed endovascular procedures.
Anticoagulation adjunctive therapy	2	
Antiplatelet adjunctive therapy	8	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 6: Past medical history significant for diabetes mellitus, hypertension, and heavy smoking. Gradually increasing claudication of bilateral lower extremities for at least 2 months. CTA pelvis with runoff reveals bilateral common iliac artery occlusion without any involvement of the external or internal iliac artery (TASC C).

Treatment/Procedure	Rating	Comments
Best medical management including supervised exercise program only	2	
Primary percutaneous transluminal angioplasty alone	6	
Primary stenting	8	
Surgical revascularization	7	
Anticoagulation adjunctive therapy	3	This procedure is not likely beneficial in the more chronic setting. It may be beneficial in addition to revascularization.
Antiplatelet adjunctive therapy	8	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 7: Worsening claudication and small ischemic ulcers on digits of both feet. Angiogram demonstrates diffuse disease involving distal aorta and both iliac vessels, with multiple stenoses >50%, bilateral 75% mid–superficial femoral artery stenosis, and 2-vessel tibial runoff bilaterally (TASC D).

Treatment/Procedure	Rating	Comments
Anticoagulation adjunctive therapy	3	
Antiplatelet adjunctive therapy	8	
Best medical management including supervised exercise program only	2	This procedure may be used as an adjunct to more definitive therapy.
Percutaneous transluminal angioplasty (aortoiliac only)	6	This procedure may be a first step. TASC C/D lesions may require stents or surgery.
Catheter directed stent placement (aortoiliac only)	7	
Catheter directed stent placement (aortoiliac plus femoral angioplasty)	8	This procedure should be part of a complete surgical plan for the patient.
Surgical revascularization	6	This procedure needs to be individualized depending on patient parameters.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

This discussion of iliac artery occlusive disease reviews the broader topic of peripheral vascular disease. Consensus documents provide a comprehensive overview of this complex topic. The consensus recommendations can be modulated by more recent literature with specific attention to iliac disease. Additionally, more recent literature review has allowed for evidence-based management in the surgical and endovascular approach of aortoiliac occlusive disease.

Iliac artery occlusive disease can present as a sudden-onset acute thrombotic event or a chronic, progressive atherosclerotic process. History and physical examination rapidly establish this distinction and determine the most appropriate application of further clinical and imaging examinations. Suspected acute thrombotic events often require rapid evaluation for limb salvage, and the methods and urgency of clinical and imaging examinations in this setting differ from those applied to progressive atherosclerotic disease. In all cases, initial physical examination by a vascular specialist should include evaluation of extremity pulses, capillary refill, skin quality, color and qualitative temperature, and evidence of tissue compromise. Lower-extremity noninvasive physiologic studies such as pulse volume recording (PVR) and ankle brachial index (ABI) are simple and valuable tools in the screening and management of the patients with chronic limb ischemia. ABI is measurement of the ankle-to-brachial systolic blood pressure ratio. Plethysmography, another uncommonly used test, detects the changes in the limb volume by PVR. Over a period of time, use of plethysmography and PVR has fallen out of favor because of their lack of reliable and reproducible quantitative data.

Overview of Diagnostic Imaging and Therapeutic Options

Diagnostic imaging is tailored to the clinical presentation and may include ultrasound (US) with Doppler vascular US, computed tomographic angiography (CTA), magnetic resonance angiography (MRA), and catheter-directed digital subtraction angiography (DSA). When considering CTA in patients with marginal renal function, dilute iso-osmolar contrast, hydration with sodium bicarbonate solution, and pretreatment with N-acetylcysteine sodium bicarbonate drip may be beneficial, although application of these options is controversial. When considering MRA, time-of-flight sequences may be used when contrast cannot be administered. Depending on the pathophysiology and clinical presentation, therapeutic options for acute thrombotic causes include supportive care, anticoagulation, thrombolytic therapy, either surgical or catheter-directed mechanical thrombectomy, and surgical bypass. Therapeutic options for atherosclerotic disease include supportive measures such as behavior modification, a supervised exercise program, adjunctive anticoagulation and antiplatelet medications, angioplasty, stent placement, stent-graft placement, surgical or catheter-directed endarterectomy/plaque excision, and surgical bypass.

Discussion of Procedures by Variant

Variant 1: Nonsmoker, Sedentary Lifestyle. No Symptoms at Rest but Mild Left Lower-extremity Claudication on Walking,

Asymmetrically Diminished Left Femoral Pulse. Next Steps on Initial Physician Visit

Chronic iliac artery occlusive disease resulting from atherosclerosis may be asymptomatic or incidentally identified on diagnostic imaging studies or may present with claudication, reproducible lower-extremity pain that is brought on by walking or exercise and relieved by rest. Typically, noninvasive screening begins with US and measurement of ABI and/or segmental arterial pressures in the outpatient clinic setting. ABIs may be normal at rest in the setting of isolated iliac occlusive disease. Arterial imaging is indicated in patients with abnormal resting ABIs or abnormal postexercise ABIs in whom revascularization would be performed if an amenable lesion was identified. Plethysmography and PVR are becoming less commonly used in most modern laboratories because of their lack of reliability and reproducibility. If findings suggest peripheral artery disease (PAD), further confirmation with CTA or MRA is usually required to determine the best application of endovascular or surgical intervention. The notion that CTA unnecessarily increases contrast load and related risks may not hold true since the CTA findings usually facilitate a marked decrease in contrast dose required for endovascular interventions. In most cases, catheter-directed DSA is performed only at the time of endovascular intervention, but in some cases, DSA may augment cross-sectional imaging options prior to intervention by providing diagnostic information regarding the patency of medium and small runoff arteries. Ultimately, catheter-directed DSA is performed in most patients prior to revascularization. Intra-arterial pressure measurements may be of value, with systolic gradients >10 mm Hg at rest or following pharmacologic challenge considered significant.

In all cases of chronic limb ischemia, medical management is a key component of treatment and should include risk factor modification such as smoking cessation and control of hyperlipidemia, diabetes, and hypertension. A lipid profile should be obtained covering total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglyceride, and (in younger patients) homocysteine levels. Medical strategies such as a supervised exercise program and antiplatelet therapies such as cilostazol or aspirin should be considered in appropriate patients, but patients with iliac lesions, as opposed to infrainguinal disease, may be considered for revascularization without undergoing extensive medical therapy. The CLEVER study demonstrated superior treadmill walking performance at 6-month follow-up in the supervised exercise cohort versus the primary stenting cohort for patients with claudication resulting from aortoiliac PAD.

Variant 2: Long History of Mild Claudication. Acute-Onset Left Lower-Extremity Pain. Absent Left Femoral Pulse on Palpation, Faint Dorsalis Pedis and Posterior Tibial Pulses by Doppler. Next Steps

Variant 3: Known Atrial Fibrillation and Spine Surgery 3 Weeks Ago. Sudden-Onset Right Lower-Extremity Pain. Diminished Pulses in Right Lower Extremity. CTA Demonstrates Isolated Filling Defect in Right Common Iliac Artery

Acute iliac artery ischemia can occur because of thromboembolism, atheroembolism, in situ native arterial thrombosis, or thrombosis of a surgical bypass graft. The goal is prompt restoration of distal blood flow. Acute-onset iliac occlusive disease typically presents as sudden-onset pain in the lower limb(s). Prompt determination of the duration and severity of symptoms and any prior surgical and endovascular procedures is essential. On clinical examination, pulses are usually diminished or absent depending upon the level of thrombosis and the severity of any coexisting atherosclerotic disease. Considering the acute nature of the presentation, screening tools such as plethysmography and PVR are usually not the diagnostic tests of choice. CTA is fast and reveals the exact nature and level of both thrombosis and underlying atherosclerotic plaque in order to plan an appropriate treatment strategy. MRA is an alternative when time permits. ABI and Doppler US may be considered in patients who are not suitable for CTA, such as patients with renal dysfunction or knee/hip prosthesis.

Patients presenting with acute limb ischemia without contraindications to anticoagulation should receive anticoagulated therapy immediately, usually with heparin. All patients, particularly those with atypical presentations, should be evaluated for hypercoagulability. This assessment may be initiated concurrently with anticoagulation therapy and may include prothrombin time, partial thromboplastin time, platelet count, and levels of factor V Leiden, factor II (prothrombin) C-20210a, anticardiolipin antibody, protein C, protein S, and antithrombin III. In addition to systemic anticoagulation, treatment options include a glycoprotein IIb/IIIa antagonist, catheter-directed thrombolysis, and mechanical thrombectomy. Ultimately, treatment of any causative underlying lesion by endovascular or surgical means is extremely important to prevent or delay the recurrence of the symptoms.

The most extensively studied and commonly used endovascular option is catheter-directed pharmacologic thrombolysis. Alteplase, reteplase, and urokinase are the most frequently used agents, and a wide variety of infusion protocols have been described. There is evidence that the glycoprotein IIb/IIIa antagonist abciximab may reduce distal emboli. US-assisted pharmacologic thrombolysis, suction embolectomy, and rheolytic therapy are broadly accepted options and may be used in conjunction with other therapies. US-assisted techniques may reduce the duration of thrombolysis infusion; suction embolectomy and rheolytic options may be particularly useful when thrombolysis is contraindicated. Surgical options include catheter embolectomy and bypass. Although there is no convincing evidence for the universal superiority of either endovascular or surgical approaches, distinguishing embolic from in situ lesions may help in planning therapy. Furthermore, the severity of ischemia and ability to tolerate surgery are important factors for consideration.

For native-vessel thrombosis, a trial of thrombolytic therapy is recommended for viable limbs. In cases where a guidewire can be passed across

the lesion, catheter-directed thrombolysis may be instituted. In cases where a guidewire cannot be successfully passed, regional thrombolysis should be attempted. Prospective, randomized trials demonstrate that 1-year limb salvage rates with endovascular techniques are similar to those following surgery, with lower mortality rates but higher rates of recurrent ischemia and amputation. The endovascular approach allows treatment of the underlying lesion following thrombolysis, and gradual low-pressure reperfusion may avoid reperfusion injury. The use of mechanical techniques may allow more prompt restoration of flow and expanded use of endovascular techniques in the threatened limb. Surgical approaches should be reserved for patients in whom thrombolysis or endovascular thrombectomy failed, for situations in which an unacceptable delay due to attempted endovascular techniques jeopardizes the viability of a limb, or for nonviable limbs.

For embolic occlusions, a consensus document recommends that isolated suprainguinal emboli be removed surgically. If embolic fragmentation and distal embolization into peripheral vessels have occurred, endovascular thrombolytic therapy is the preferred therapeutic option. Echocardiography is not necessary prior to thrombolytic therapy for embolic disease.

For occluded aortoiliac or aortofemoral bypass grafts, catheter-directed thrombolysis is the preferred option in grafts occluded <14 days. Despite a higher risk of amputation, catheter-directed therapy allows underlying lesions to be defined and treated. Furthermore, surgical risks related to reoperative anatomy and wound complications can be avoided. Following management of an acute thrombotic event, these patients should undergo consultation for appropriate medical management of risk factors, a supervised exercise program, and initiation of antiplatelet therapy.

Variant 4: Past Medical History of Heavy Smoking. Severe Claudication and No Symptoms at Rest. Angiogram Demonstrates Bilateral 90% Common Iliac Artery Stenosis (TASC A)

Variant 5: Past Medical History Significant for Diabetes Mellitus, Hypertension, and Smoking. Increasing Claudication of Right Lower Extremity Involving Right Buttock for Last 3 Months. CTA Pelvis with Runoff Reveals Short-Segment Occlusion of Right Common Iliac Artery (TASC B)

Variant 6: Past Medical History Significant for Diabetes Mellitus, Hypertension, and Heavy Smoking. Gradually Increasing Claudication of Bilateral Lower Extremities for at Least 2 Months. CTA Pelvis with Runoff Reveals Bilateral Common Iliac Artery Occlusion without Any Involvement of the External or Internal Iliac Artery (TASC C)

Variant 7: Worsening Claudication and Small Ischemic Ulcers on Digits of Both Feet. Angiogram Demonstrates Diffuse Disease Involving Distal Aorta and Both Iliac Vessels, with Multiple Stenoses >50%, Bilateral 75% Mid–superficial Femoral Artery Stenosis, and 2-Vessel Tibial Runoff Bilaterally (TASC D)

Chronic iliac arterial occlusive disease is chronic, progressive atherosclerosis that may remain asymptomatic or present with claudication. In severe cases (ABI <0.4), patients present with rest pain or critical limb ischemia (CLI) with associated ulcers or gangrene. Although iliac occlusive disease is commonly a contributing factor to CLI, it seldom exists as an isolated lesion. Noninvasive evaluation includes ABI, segmental arterial pressures, US, and either CTA or MRA to plan either endovascular or surgical intervention. The Trans-Atlantic Inter-Society Consensus (TASC) Management of Peripheral Arterial Disease document described anatomic classification and therapeutic recommendations for iliac occlusive disease. TASC II has modified these recommendations for consistency; the TASC II classification scheme was used to describe Variants 4 through 7. Endovascular therapy is the treatment of choice for TASC A and B lesions, and recent studies confirm an expanded role for endovascular therapy in TASC C and D lesions, which were historically treated with surgical options.

Percutaneous Transluminal Angioplasty versus Stent

The Dutch iliac stent trial concluded that percutaneous transluminal angioplasty (PTA) with selective stent placement yielded patency rates similar to those occurring with primary stenting. More recent stratified studies have documented that primary angioplasty with selective stenting is effective for TASC A and B lesions. However, stenting has demonstrated significant benefits over angioplasty alone in TASC C and D lesions. A recent large meta-analysis demonstrated significantly higher 12-month primary patency rates for primary stenting (92.1%; 95% confidence interval [CI], 89.0%–94.3%) in comparison to selective stenting (82.9%; 95% CI, 72.2%–90.0%) for TASC C and D lesions. Other authors have found patency rates for primary stenting of TASC C and D lesions to be similar to those for TASC A and B lesions. Finally, a recent study found no significant difference in the patency rates of iliac artery stents among all TASC categories, questioning the utility of the TASC classification and associated endovascular and surgical recommendations in iliac disease. It appears that primary stenting is the preferred treatment for most patients with TASC A-D lesions. However, primary stenting has demonstrated significantly higher complication rates in TASC C and D lesions in comparison to TASC A and B lesions.

Bare Metal versus Covered Stent

With respect to the role of stents covered with polytetrafluoroethylene in treating iliac occlusive disease, 2 studies have confirmed its technical feasibility, and both demonstrated 1-year primary patency rates of 91%. One report described a significant benefit of using covered balloon-

expandable stents in type C and D lesions as compared to bare metal stents at 18-month follow-up with respect to binary restenosis (95.4% versus 82.2%), amputation rate (1.2% versus 3.6%), and clinical improvement (94.2% versus 76.7%). Another study demonstrated significantly higher 5-year primary patency rates with the use of stent grafts as compared to bare metal stents (87% versus 53%) in patients undergoing simultaneous common femoral artery (CFA) endarterectomy and iliac revascularization. Additional information regarding patency rates of covered stents will also be provided by long-term review of aortic endograft experience.

Surgery versus Endovascular Therapy

For TASC C and D lesions, surgery has historically been recommended; however, more recent data suggest an expanded role for endovascular therapy. Meta-analysis of long-term results for aortofemoral bypass grafts for iliac disease demonstrated 5-year limb-based patency rates of 90% in claudicants and 87% in patients with CLI. Two recent studies comparing surgical aortofemoral bypass to aortoiliac angioplasty and stenting demonstrate similar results. Surgical bypass yielded higher 3-year primary patency rates and greater improvement in ABIs but at the cost of increased surgical complication rates, including the need for emergency surgery, infection, transfusion, and lymph leak. Endovascular therapy shortens the initial hospitalization stay and is associated with half the number of readmissions. Importantly, neither study demonstrated a significant difference in secondary patency rates, limb salvage, or long-term survival.

The durability of endovascular recanalization of the iliac arteries has been established, although primary patency is generally less than that of surgery. A recent study involving iliac recanalization demonstrated 1-, 2-, and 3-year primary patency rates of 86%, 76%, and 68%, respectively. Secondary patency rates were 94%, 92%, and 80%, respectively. Another study has reported 3-, 5-, 7-, and 10-year primary patency rates of 90%, 85%, 80%, and 68%, respectively. Despite substantial variation between these studies, the long-term patency of recanalized iliac segments has proven satisfactory. The more recent BRAVISSIMO study demonstrated primary patency rates at 24 months for TASC A, B, C, and D lesions of 88.0%, 88.5%, 91.9%, and 84.8.2%, respectively, with no statistical difference when comparing the 4 groups, suggesting endovascular therapy is the preferred treatment for patients with TASC A-D aortoiliac lesions. Additionally, a recent meta-analysis comprising 16 studies and 958 patients evaluates endovascular therapy for TASC D lesions and demonstrates technical success and 12-month primary patency rates of 90.1% and 87.3%, respectively. Bifurcated endografts demonstrated a technical success rate of 100% and promising long-term results in TASC C and D lesions in a recent study.

Surgical intervention incurs higher morbidity, including risk of impotence and retrograde ejaculation; endovascular therapies allow greater ease of reintervention. With perpetual improvements in both technology and operator experience, several recent studies have further demonstrated adequate evidence of safety and efficacy with subintimal recanalization and re-entry into the true lumen, with success rates ranging from 71% to 100%. Additionally, subintimal revascularization has demonstrated success and safety in chronic total iliac artery occlusions, including long-segment (>5 cm) occlusions. The TASC authors have noted that when choosing between endovascular and open-surgical/bypass therapies with equivalent short-term and long-term outcomes, endovascular techniques should be used first.

Endovascular Adjunct to Other Procedures

Endovascular therapy may be an adjunct to a separate surgical or endovascular procedure. It has been demonstrated that an ipsilateral stenotic, but not occluded, superficial femoral artery (SFA) is a predictor of iliac intervention failure and that SFA stenoses should be addressed at the time of iliac intervention. When iliac intervention is performed in conjunction with infrainguinal surgical bypass, graft patency is significantly greater with stenting as compared to angioplasty alone and is similar to that of aortofemoral bypass at 5 years. For external iliac artery disease that extends into the CFA, external iliac artery stent placement with CFA endarterectomy and patch angioplasty has produced durable results with less extensive surgery than conventional bypass. One study evaluating the combined CFA endarterectomy with stenting of the common or external iliac artery demonstrated a 5-year primary patency rate of 60% and a secondary patency rate of 98%. Endovascular repair and femoral-femoral bypass may be useful in patients with a stenotic segment <5 cm in the inflow limb and contralateral iliac occlusion but not in patients with stenoses >5 cm (primary patency rates at 3 years are 85% and 31%, respectively).

Predictors of Success and Failure

Multivariate analysis of independent predictors for iliac intervention failure has described a 3-year primary patency rate of iliac intervention of 36% for untreated stenotic (>50%) for SFAs in the setting of iliac artery angioplasty or stent. SFAs that are occluded, patent, or receiving concomitant angioplasty at the time of iliac intervention demonstrated 3-year primary patency rates of 84%, 81%, and 75%, respectively. Occluded SFAs can be observed, but stenotic SFAs should be repaired at the time of iliac intervention. Hypertension, hypercholesterolemia, chronic renal insufficiency, poor tibial runoff, external iliac artery disease, female gender, smoking, gangrene, ulcer, diabetes mellitus, presence of a distal bypass, and hormone replacement therapy in female patients are all independent predictors of failure. Immediate hemodynamic improvement and the presence of 2-vessel femoral or 2-vessel tibial runoff have been found to be predictors of favorable outcome. In addition, these patients should undergo consultation for medical management of risk factors, a supervised exercise program, and initiation of antiplatelet therapy.

Summary of Recommendations

- For patients with mild claudication, noninvasive screening with US and measurement of ABI and/or segmental arterial pressures followed by confirmation with CTA or MRA, if indicated, are recommended on the initial physician visit. Once the diagnosis of peripheral vascular disease is confirmed, a supervised exercise program and risk factor modification such as smoking cessation and control of hyperlipidemia, diabetes, and hypertension are recommended.
- For the diagnosis of the acute thromboembolic event, CTA is fast and reveals the exact nature and level of both thrombosis and underlying atherosclerotic plaque. MRA is an alternative when time permits. Doppler US may be considered in patients who are not suitable for CTA, such as patients with renal dysfunction or knee/hip prosthesis.
- An isolated acute embolic event involving the common iliac artery is best treated by surgical revascularization. Catheter-directed mechanical thrombectomy is usually appropriate. Anticoagulation is usually indicated except in situations such as recent surgery.
- For TASC A lesions, bilateral percutaneous transluminal angioplasty alone or in combination with stent placement in patients with suboptimal results after PTA and adjunctive antiplatelet therapy is usually appropriate.
- For TASC B lesions, bilateral percutaneous transluminal angioplasty alone or in combination with stent placement in patients with suboptimal results after PTA and adjunctive antiplatelet therapy is usually appropriate.
- For TASC C lesions, primary stenting combined with antiplatelet therapy is usually the first choice, followed by open surgery if endovascular therapy fails.
- For TASC D lesions, catheter-directed aortoiliac stent/stent-graft placement with or without femoral angioplasty combined with antiplatelet therapy is usually the first choice, followed by open surgery if endovascular therapy fails.

Abbreviations

- ABIs, ankle-brachial indices
- CTA, computed tomography angiography
- MRA, magnetic resonance angiography
- TASC, Trans-Atlantic Inter-Society Consensus
- US, ultrasound

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Iliac artery occlusive disease

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Cardiology

Internal Medicine

Radiology

Surgery

Intended Users

Advanced Practice Nurses

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Physician Assistants

Physicians

Students

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of imaging and other procedures for evaluation and treatment of iliac artery occlusive disease

Target Population

Patients with iliac artery occlusive disease

Interventions and Practices Considered

1. Duplex Doppler ultrasound, lower extremity
2. Plethysmography and pulse volume recording
3. Computed tomography angiography (CTA), pelvis with runoff
4. Magnetic resonance angiography (MRA), pelvis with runoff
5. Catheter-directed angiography
6. Risk factor analysis, lipid profile and ankle-brachial indices (ABIs)
7. No further treatment or evaluation
8. Best medical management including supervised exercise program only
9. Anticoagulation adjunctive therapy
10. Antiplatelet adjunctive therapy
11. Catheter-directed thrombolytic therapy
12. Catheter-directed mechanical thrombectomy
13. Surgical revascularization
14. Bilateral percutaneous transluminal angioplasty only
15. Bilateral stent placement
16. Primary percutaneous transluminal angioplasty alone
17. Primary stenting
18. Percutaneous transluminal angioplasty (aortoiliac only)
19. Catheter-directed stent placement
    - Aortoiliac only
    - Aortoiliac plus femoral angioplasty

Major Outcomes Considered

- Mortality rate
- Rate of recurrent ischemia
- Rate of amputation
- Primary and secondary patency rates
- Limb salvage rates

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Summary

Of the 33 citations in the original bibliography, 30 were retained in the final document. Articles were removed from the original bibliography if they were more than 10 years old and did not contribute to the evidence or they were no longer cited in the revised narrative text.

A new literature search was conducted in April 2015 to identify additional evidence published since the *ACR Appropriateness Criteria® Radiologic Management of Iliac Artery Occlusive Disease* topic was finalized. Using the search strategy described in the literature search companion (see the "Availability of Companion Documents" field), 173 articles were found. Nine articles were added to the bibliography. One hundred and sixty-four articles were not used due to either poor study design, the articles were not relevant or generalizable to the topic, the results were unclear, misinterpreted, or biased, or the articles were already cited in the original bibliography.

The author added 8 citations from bibliographies, Web sites, or books that were not found in the new literature search.

See also the American College of Radiology (ACR) Appropriateness Criteria® literature search process document (see the "Availability of Companion Documents" field) for further information.

Number of Source Documents

Of the 33 citations in the original bibliography, 30 were retained in the final document. The new literature search conducted in April 2015 identified 9 articles that were added to the bibliography. The author added 8 citations from bibliographies, Web sites, or books that were not found in the new literature search.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Definitions of Study Quality Categories

Category 1 - The study is well-designed and accounts for common biases.

Category 2 - The study is moderately well-designed and accounts for most common biases.

Category 3 - The study has important study design limitations.

Category 4 - The study or source is not useful as primary evidence. The article may not be a clinical study, the study design is invalid, or conclusions are based on expert consensus.

> The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);
>
> *Or*
>
> The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;
>
> *Or*
>
> The study is an expert opinion or consensus document.

Category M - Meta-analysis studies are not rated for study quality using the study element method because the method is designed to evaluate individual studies only. An "M" for the study quality will indicate that the study quality has not been evaluated for the meta-analysis study.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author assesses the literature then drafts or revises the narrative summarizing the evidence found in the literature. American College of Radiology (ACR) staff drafts an evidence table based on the analysis of the selected literature. These tables rate the study quality for each article included in the narrative.

The expert panel reviews the narrative, evidence table and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the variant table(s). Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The American College of Radiology (ACR) Appropriateness Criteria (AC) methodology is based on the RAND Appropriateness Method. The appropriateness ratings for each of the procedures or treatments included in the AC topics are determined using a modified Delphi method. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. The expert panel members review the evidence presented and assess the risks or harms of doing the procedure balanced with the benefits of performing the procedure. The direct or indirect costs of a procedure are not considered as a risk or harm when determining appropriateness. When the evidence for a specific topic and variant is uncertain or incomplete, expert opinion may supplement the available evidence or may be the sole source for assessing the appropriateness.

The appropriateness is represented on an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category

"usually not appropriate" where the harms of doing the procedure outweigh the benefits; and 7, 8, or 9 are in the category "usually appropriate" where the benefits of doing a procedure outweigh the harms or risks. The middle category, designated "may be appropriate," is represented by 4, 5, or 6 on the scale. The middle category is when the risks and benefits are equivocal or unclear, the dispersion of the individual ratings from the group median rating is too large (i.e., disagreement), the evidence is contradictory or unclear, or there are special circumstances or subpopulations which could influence the risks or benefits that are embedded in the variant.

The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating. To determine the panel's recommendation, the rating category that contains the median group rating without disagreement is selected. This may be determined after either the first or second rating round. If there is disagreement after the first rating round, a conference call is scheduled to discuss the evidence and, if needed, clarify the variant or procedure description. If there is disagreement after the second rating round, the recommendation is "May be appropriate."

This modified Delphi method enables each panelist to articulate his or her individual interpretations of the evidence or expert opinion without excessive influence from fellow panelists in a simple, standardized, and economical process. For additional information on the ratings process see the Rating Round Information document.

Additional methodology documents, including a more detailed explanation of the complete topic development process and all ACR AC topics can be found on the ACR Web site (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current medical evidence literature and the application of the RAND/UCLA appropriateness method and expert panel consensus.

Summary of Evidence

Of the 47 references cited in the *ACR Appropriateness Criteria® Radiologic Management of Iliac Artery Occlusive Disease* document, 43 are categorized as therapeutic references including 10 well-designed studies, 25 good-quality studies, and 1 quality study that may have design limitations. Additionally, 2 references are categorized as diagnostic references. There are 9 references (including the 2 diagnostic references) that may not be useful as primary evidence. There are 2 references that are meta-analysis studies.

Most of the references are well-designed or good-quality studies and provide good evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate and timely selection of diagnostic imaging and therapeutic procedures for patients with iliac artery occlusive disease presenting as either an acute thrombotic event or chronic atherosclerotic disease

Potential Harms

- Surgical intervention incurs higher morbidity, including risk of impotence and retrograde ejaculation, compared with endovascular therapies.
- Primary stenting has demonstrated significantly higher complication rates in Trans-Atlantic Inter-Society Consensus (TASC) C and D lesions in comparison to TASC A and B lesions.
- Surgical bypass yielded higher 3-year primary patency rates and greater improvement in ankle-brachial indices (ABIs) but at the cost of increased surgical complication rates, including the need for emergency surgery, infection, transfusion, and lymph leak.

Contraindications

Contraindications

Anticoagulation is potentially contraindicated in the setting of recent spinal surgery.

Qualifying Statements

Qualifying Statements

- The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.
- ACR seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply society endorsement of the final document.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report

Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Safety

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Copelan AZ, Kapoor BS, AbuRahma AF, Cain TR, Caplin DM, Farsad K, Knuttinen MG, Lee MH, McBride JJ, Minocha J, Reis SP, Rochon PJ, Shaw CM, Lorenz JM, Expert Panel on Interventional Radiology. ACR Appropriateness CriteriaÂ® radiologic management of iliac artery occlusive disease. Reston (VA): American College of Radiology (ACR); 2017. 12 p. [47 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Interventional Radiology

Composition of Group That Authored the Guideline

Panel Members: Alexander Z. Copelan, MD (*Research Author*); Baljendra S. Kapoor, MB, BS (*Principal Author and Panel Chair*); Ali F. AbuRahma, MD; Thomas R. Cain, MD; Drew M. Caplin, MD; Khashayar Farsad, MD, PhD; M-Grace Knuttinen, MD, PhD; Margaret H. Lee,

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Financial Disclosures/Conflicts of Interest

All panel members, authors, and chairs must complete a Conflict of Interest and Expertise Survey annually, disclosing any actual or potential conflicts related to duties and responsibilities on the panel.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Kostelic JK, Ray CE Jr, Lorenz JM, Burke CT, Darcy MD, Fidelman N, Hohenwalter EJ, Kinney TB, Kolbeck KJ, Kouri BE, Mansour MA, Nair AV, Owens CA, Rochon PJ, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® radiologic management of iliac artery occlusive disease. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 8 p. [33 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American College of Radiology (ACR) Web site .

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2015 Oct. 3 p. Available from the American College of Radiology (ACR) Web site .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2015 Feb. 1 p. Available from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development. Reston (VA): American College of Radiology; 2015 Nov. 5 p. Available from the ACR Web site .
- ACR Appropriateness Criteria®. Topic development process. Reston (VA): American College of Radiology; 2015 Nov. 2 p. Available from the ACR Web site .
- ACR Appropriateness Criteria®. Rating round information. Reston (VA): American College of Radiology; 2015 Apr. 5 p. Available from the ACR Web site .
- ACR Appropriateness Criteria® radiologic management of iliac artery occlusive disease. Evidence table. Reston (VA): American College of Radiology; 2017. 31 p. Available from the ACR Web site .
- ACR Appropriateness Criteria® radiologic management of iliac artery occlusive disease. Literature search. Reston (VA): American College of Radiology; 2017. 1 p. Available from the ACR Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on May 12, 2010. This summary was updated by ECRI Institute on July 27, 2010 following the FDA drug safety communication on Heparin. This summary was updated by ECRI Institute on September 23, 2012. This summary was updated by ECRI Institute on March 10, 2014 following the U.S. Food and Drug Administration advisory on Low Molecular Weight

Heparins. This summary was updated by ECRI Institute on June 23, 2017.

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